

Remarks

Claims 51-61 are pending in the subject application. Applicants acknowledge that claims 60 and 61 have been withdrawn from further consideration as being drawn to a non-elected invention. By this Amendment, Applicants have canceled claims 51-61 and added new claims 62-70. Support for the new claims can be found throughout the subject specification (see, for example, paragraph 45) and in the claims as originally filed. Entry and consideration of the new claims presented herein is respectfully requested. Accordingly, claims 62-70 are currently before the Examiner with claims 69 and 70 standing withdrawn from consideration. Favorable consideration of the pending claims is respectfully requested.

The specification is objected to because of the following informalities: the title of the invention is not descriptive. Applicants have adopted the Examiner's suggestion and changed the title of the invention to: "Biosynthetic Genes and Host Cells for the Synthesis of Polyketide Antibiotics and Method of Use." Accordingly, reconsideration and withdrawal of the objection is respectfully requested.

The specification is objected to because of the following informalities: Figures 3-7 and 10 disclose sequences, however, the Brief Description of the Drawing does not report the corresponding SEQ ID NO. Applicants have revised the Examples to provide SEQ ID NOs. for the pertinent sequences found in the figures and respectfully submit that this issue is now moot. In addition, a replacement sequence listing has been provided and the necessary paragraph added to the subject specification. I hereby certify that no new material is being added by this submission. Accordingly, reconsideration and withdrawal of the objections is respectfully requested.

Claims 52 and 55 are objected to because of the following informalities: claim 52 depends from a rejected base claim and claim 55(j) is suggested by the Examiner to be amended to read, "isolated polynucleotide sequence." Applicants thank the Examiner for her careful review of the claims and have rewritten the new claims in a fashion that renders this issue moot. Accordingly, reconsideration and withdrawal of the objections is respectfully requested.

Claims 54-59 are rejected under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the

claimed invention. The Office Action argues that the as-filed specification fails to provide adequate written description for the fragments of SEQ ID NOS: 1, 2 and 3 previously recited within the claims. Applicants respectfully disagree and traverse.

Previously pending claim 54 recites “a combination of nucleotide fragments of SEQ ID NOS:1-3.” The specification identifies these sequences as DNA sequences as physically separate coding regions of *X. albilineans* DNA that provide a biosynthetic pathway for the production of albidicin. These sequences represent the genetic clusters XALB1, XALB2, and XALB3 which contain the 22 genes necessary for albidicin biosynthesis. Applicants have provided SEQ ID NOS:1-3 (nucleotide sequences for XALB1, XALB2, and XALB3) and have also elucidated the functional components of SEQ ID NOS:1-3 by reading frame analysis (Example 5). In addition to examining the functions of each individual gene, Applicants used the claimed genetic sequences to create genetic constructs for the ultimate purpose of albidicin biosynthesis (page 48 of the specification). Applicants also maintain that the inclusion of SEQ ID NOS:4-47 and/or SEQ ID NOS: 4-25 specifically identify the individual genetic elements of SEQ ID NOS:1-3 necessary for albidicin biosynthesis and exemplify Applicants’ possession of polynucleotide fragments derived from SEQ ID NOS: 1, 2 and 3. Accordingly, withdrawal of the rejection under 35 U.S.C. § 112, first paragraph, is respectfully requested.

Claims 53 and 55 are rejected under 35 U.S.C. § 112, second paragraph, as failing to set forth the subject matter, which applicant(s) regard as their invention. With respect to the issue noted in claims 53 and 55, it is respectfully submitted that the new claims have rendered these issues moot and reconsideration and withdrawal of the rejection is respectfully requested.

Claims 51 and 54-59 are rejected under 35 U.S.C. § 102(b) as being anticipated by Huang *et al.* (2000). The Office Action argues that the disclosure of Huang *et al.* anticipates the claimed invention and notes that Huang *et al.* teach a gene (*xabA*) for albidicin biosynthesis and teach the use of a host cell such as *E.coli* for production of albidicin. Applicants respectfully disagree with the Examiner’s finding of anticipation. As the Patent Office is aware, a claim is anticipated only if each and every element as set forth in the claim is found, either expressly or inherently described, in a single prior art reference.” *Verdegaal Bros. v. Union Oil Co. of California*, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987). Claim 51 requires a “genetic construct that comprises SEQ

ID NO: 1, SEQ ID NO: 2, **and** SEQ ID NO: 3 (emphasis added). Huang *et al.* fail to teach these additional sequences; thus, anticipation of the claimed invention cannot exist. Applicants also disagree with the Examiner's determination that Huang *et al.* teach the use of *E. coli* for albicidin production. Huang *et al.* specifically note the inability of *E. coli* to produce albicidin upon addition of clones spanning the putative main albicidin biosynthesis region (page 198, col. 2, paragraph 3). Accordingly, reconsideration and withdrawal of the rejection under 35 U.S.C. § 102(b) is respectfully requested.

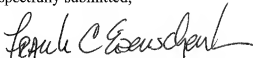
It should be understood that the amendments presented herein have been made solely to expedite prosecution of the subject application to completion and should not be construed as an indication of Applicants' agreement with or acquiescence in the Examiner's position. Applicants expressly reserve the right to pursue the invention(s) disclosed in the subject application, including any subject matter canceled or not pursued during prosecution of the subject application, in a related application.

In view of the foregoing remarks and amendments to the claims, Applicants believe that the currently pending claims are in condition for allowance, and such action is respectfully requested.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16 or 1.17 as required by this paper to Deposit Account No. 19-0065.

Applicants invite the Examiner to call the undersigned if clarification is needed on any of this response, or if the Examiner believes a telephonic interview would expedite the prosecution of the subject application to completion.

Respectfully submitted,



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Attachment: New pages 1-180 (Sequence Listing) of the subject specification